

SEP 22 2005

510(k) Summary

K052461

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR §807.92.

I. GENERAL INFORMATION

Establishment:

- Address: Siemens AG, Medical Solutions
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Germany
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- Contact Person: Eva Reiter
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Device Name and Classification:

- Trade Name: syngo® Imaging
Version V20A
- Classification Name: Picture Archiving and Communications System
- Classification Panel: Radiology
- CFR Section: 21 CFR §892.2050
- Device Class: Class II
- Product Code: LLZ

II. SAFETY AND EFFECTIVENESS INFORMATION SUPPORTING THE SUBSTANTIAL EQUIVALENCE DETERMINATION

• **Device Description and Intended Use:**

This premarket notification covers Siemens' enhanced PACS system syngo® Imaging, version V20A.

syngo® Imaging is a Picture Archiving and Communication System (PACS) intended to display, process, read, report, communicate, distribute, store and archive digital radiological images, including digital mammography images.

It supports the physician in diagnosis and treatment planning.

syngo® Imaging also supports storage and archiving of Structured DICOM Reports.

In a comprehensive imaging suite *syngo*® Imaging integrates Radiology Information Systems (RIS) to enable customer specific workflows.

Enhanced *syngo*® Imaging workplaces use a variety of advanced postprocessing applications.

The system is a "hardware independent" solution to be distributed either as software only or combined with common IT hardware which must comply to predefined minimum hardware requirements.

The version V20A contains improvements for workplace functionality, such as layout enhancements and display improvements (user interface) and amended functionality.

syngo® Imaging Workplaces

The three *syngo*® Imaging workplace deployments ...

- a) *syngo*® Web Studio - a web-based viewing application mainly used for image distribution
- b) *syngo*® Basic Studio - for basic reporting, inside as well as outside of the radiology (standalone workstation)
- c) *syngo*® Advanced Studio - Advanced Application Bundle - for use inside the radiology with advanced reporting functionality

... are medical diagnostic and viewing workstations intended for postprocessing, reading, reporting, viewing and communicating / distributing of radiological softcopy images (including digital mammographic images) and so allow radiologists and radiological technicians to receive and process all data needed.

Based on Siemens *syngo*® software, the *syngo*® Imaging supports the wide variety of image types and its modular design and is capable of combining applications from different modalities in one workstation.

The *syngo*® Advanced Studio integrates the modality specific application package *syngo*® CT Colonography (K042605).

By usage of specific FDA approved monitors (Barco: Coronis dual head 21.3" Medical - K042221; Siemens AG: SMVD 21500 or DjSB-2103-D-5MP - K043122; Planar, Dome C5i-1 and C5i-2 - K032202) diagnosis on digital mammography images is possible, if images are not compressed lossy, as disclaimed respectively.

syngo® Imaging Data Management

... ensures all authorized personnel fast and continuous access to radiological data. It's main functionality ranges from availability of images having regard to data security, open interfaces, storage media, central system administration, back-up, software distribution to providing a flexible storage hierarchy.

The main purpose is storing and archiving of radiological softcopy images and structured (DICOM) reports.

For PACS server the *syngo*® Imaging Data Management can be used as a DICOM-Archive (LTS Longterm Storage) in accordance with the DICOM Conformance Statement.

Integration:

The Workflow Management enables by integration of any HL7- / DICOM-compatible RIS (IHE Year 5) to the *syngo*® Imaging PACS a consistent workflow – from patient registration to requirement scheduling to a personal worklist and supports therefore reporting, documentation or administrative tasks.

• **Technological Characteristics:**

syngo® Imaging (version V20A) is a “software only”-system, which will be delivered on CD-ROM / DVD or as a complete radiology solution consisting of common IT hardware and pre-installed software. *syngo*® Imaging will be installed by Siemens service engineers.

Defined Hardware requirements are to be met.

The backend communication and storage solution (DM) is based on the Solaris 8 operating system. The workplaces are based on Windows XP, as well as LINUX and IBM operating systems.

The herewith described *syngo*® Imaging supports DICOM formatted images and objects.

• **General Safety and Effectiveness Concerns:**

The device labelling contains instructions for use and any necessary cautions and warning, to provide for safe and effective use of the device.

Risk management is ensured via a risk analysis, which is used to identify potential hazards. These potential hazards are controlled via software development, verification and validation testing. To minimize electrical, mechanical, and radiation hazards, Siemens adheres to recognized and established industry practice and standards.

• **Substantial Equivalence:**

The *syngo*® Imaging, addressed in this premarket notification, is substantially equivalent to the following commercially available devices:

Siemens	SIENET Cosmos	K042832
Siemens	LEONARDO	K040970
Siemens	MammoReport Softcopy Workstation	K042868

The *syngo*® Imaging described in this 510(k) has the same intended use and similar technical characteristics as the devices listed above in regard to the specific functionalities.

In summary, Siemens is of the opinion that *syngo*® Imaging does not introduce any new potential safety risks and is substantially equivalent to and performs as well as the predicate devices.



SEP 22 2005

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Siemens AG Medical Solutions
% Mr. Stefan Preiss
Responsible Third Party Official
TÜV America, Inc.
TÜV Product Service
1775 Old Highway 8
NEW BRIGHTON MN 55112-1891

Re: K052461
Trade/Device Name: syngo® Imaging (Version V20A)
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and
communications system
Regulatory Class: II
Product Code: LLZ
Dated: September 1, 2005
Received: September 8, 2005

Dear Mr. Preiss:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number (if known): K052461

Device Name: syngo® Imaging (version V20A)

Indications For Use:

syngo® Imaging is a Picture Archiving and Communication System (PACS) intended to display, process, read, report, communicate, distribute, store and archive digital radiological images, including digital mammography images.

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Prescription Use X ~~AND~~ / OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (Part 21 CFR 801 Subpart C)

(Please do not write below this line - continue on another page if needed)

Concurrence of the CDRH, Office of Device Evaluation (ODE)

David R. Lyscom

(Division Sign-Off)

Division of Reproductive, Abdominal,
and Radiological Devices

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